



General

Guideline Title

Guidelines for the diagnosis and management of gastroesophageal reflux disease.

Bibliographic Source(s)

Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013 Mar;108(3):308-28. [184 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The definitions for quality of evidence (high, moderate, low, and very low) and strength of recommendations (strong or conditional) are provided at the end of the "Major Recommendations" field.

Establishing the Diagnosis of Gastroesophageal Reflux Disease (GERD)

- 1. A presumptive diagnosis of GERD can be established in the setting of typical symptoms of heartburn and regurgitation. Empiric medical therapy with a proton pump inhibitor (PPI) is recommended in this setting. (Strong recommendation, moderate level of evidence)
- 2. Patients with non-cardiac chest pain suspected due to GERD should have diagnostic evaluation before institution of therapy. (Conditional recommendation, moderate level of evidence) A cardiac cause should be excluded in patients with chest pain before the commencement of a gastrointestinal evaluation. (Strong recommendation, low level of evidence)
- 3. Barium radiographs should not be performed to diagnose GERD. (Strong recommendation, high level of evidence)
- 4. Upper endoscopy is not required in the presence of typical GERD symptoms. Endoscopy is recommended in the presence of alarm symptoms and for screening of patients at high risk for complications. Repeat endoscopy is not indicated in patients without Barrett's esophagus in the absence of new symptoms. (Strong recommendation, moderate level of evidence)
- 5. Routine biopsies from the distal esophagus are not recommended specifically to diagnose GERD. (Strong recommendation, moderate level of evidence)
- 6. Esophageal manometry is recommended for preoperative evaluation, but has no role in the diagnosis of GERD. (Strong recommendation, low level of evidence)
- 7. Ambulatory esophageal reflux monitoring is indicated before consideration of endoscopic or surgical therapy in patients with non-erosive disease (NERD), as part of the evaluation of patients refractory to PPI therapy, and in situations when the diagnosis of GERD is in question. (Strong recommendation, low level of evidence) Ambulatory reflux monitoring is the only test that can assess reflux symptom association.

- (Strong recommendation, low level of evidence)
- 8. Ambulatory reflux monitoring is not required in the presence of short or long-segment Barrett's esophagus to establish a diagnosis of GERD. (Strong recommendation, moderate level of evidence)
- 9. Screening for *Helicobacter pylori* infection is not recommended in GERD patients. Treatment of *H. pylori* infection is not routinely required as part of antireflux therapy. (Strong recommendation, low level of evidence)

Management of GERD

- 1. Weight loss is recommended for GERD patients who are overweight or have had recent weight gain. (Conditional recommendation, moderate level of evidence)
- 2. Head of bed elevation and avoidance of meals 2–3 hours before bedtime should be recommended for patients with nocturnal GERD. (Conditional recommendation, low level of evidence)
- 3. Routine global elimination of food that can trigger reflux (including chocolate, caffeine, alcohol, acidic and/or spicy foods) is not recommended in the treatment of GERD. (Conditional recommendation, low level of evidence)
- 4. An 8-week course of PPIs is the therapy of choice for symptom relief and healing of erosive esophagitis. There are no major differences in efficacy between the different PPIs. (Strong recommendation, high level of evidence)
- 5. Traditional delayed release PPIs should be administered 30–60 minutes before meal for maximal pH control. (Strong recommendation, moderate level of evidence) Newer PPIs may offer dosing flexibility relative to meal timing. (Conditional recommendation, moderate level of evidence)
- 6. PPI therapy should be initiated at once a day dosing, before the first meal of the day. (Strong recommendation, moderate level of evidence)
 For patients with partial response to once daily therapy, tailored therapy with adjustment of dose timing and/or twice daily dosing should be considered in patients with night-time symptoms, variable schedules, and/or sleep disturbance. (Strong recommendation, low level of evidence)
- 7. Non-responders to PPI should be referred for evaluation. (Conditional recommendation, low level of evidence, see refractory GERD section)
- 8. In patients with partial response to PPI therapy, increasing the dose to twice daily therapy or switching to a different PPI may provide additional symptom relief. (Conditional recommendation, low level evidence)
- 9. Maintenance PPI therapy should be administered for GERD patients who continue to have symptoms after the PPI is discontinued, and in patients with complications including erosive esophagitis and Barrett's esophagus. (Strong recommendation, moderate level of evidence) For patients who require long-term PPI therapy, it should be administered in the lowest effective dose, including on demand or intermittent therapy. (Conditional recommendation, low level of evidence)
- 10. Histamine-receptor antagonists (H₂RA) therapy can be used as a maintenance option in patients without erosive disease if patients experience heartburn relief. (Conditional recommendation, moderate level of evidence) Bedtime H₂RA therapy can be added to daytime PPI therapy in selected patients with objective evidence of night-time reflux if needed, but may be associated with the development of tachyphylaxis after several weeks of usage. (Conditional recommendation, low level of evidence)
- 11. Therapy for GERD other than acid suppression, including prokinetic therapy and/or baclofen, should not be used in GERD patients without diagnostic evaluation. (Conditional recommendation, moderate level of evidence)
- 12. There is no role for sucralfate in the non-pregnant GERD patient. (Conditional recommendation, moderate level of evidence)
- 13. PPIs are safe in pregnant patients if clinically indicated. (Conditional recommendation, moderate level of evidence)

Surgical Options for GERD

- 1. Surgical therapy is a treatment option for long-term therapy in GERD patients. (Strong recommendation, high level of evidence)
- 2. Surgical therapy is generally not recommended in patients who do not respond to PPI therapy. (Strong recommendation, high level of evidence)
- 3. Preoperative ambulatory pH monitoring is mandatory in patients without evidence of erosive esophagitis. All patients should undergo preoperative manometry to rule out achalasia or scleroderma-like esophagus. (Strong recommendation, moderate level of evidence)
- 4. Surgical therapy is as effective as medical therapy for carefully selected patients with chronic GERD when performed by an experienced surgeon. (Strong recommendation, high level of evidence)
- 5. Obese patients contemplating surgical therapy for GERD should be considered for bariatric surgery. Gastric bypass would be the preferred operation in these patients. (Conditional recommendation, moderate level of evidence)
- 6. The usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy. (Conditional recommendation, moderate level of evidence)

- 1. Switching PPIs can be considered in the setting of side effects. (Conditional recommendation, low level of evidence)
- 2. Patients with known osteoporosis can remain on PPI therapy. Concern for hip fractures and osteoporosis should not affect the decision to use PPI long-term except in patients with other risk factors for hip fracture. (Strong recommendation, moderate level of evidence)
- 3. PPI therapy can be a risk factor for *Clostridium difficile* infection, and should be used with care in patients at risk. (Strong recommendation, moderate level of evidence)
- 4. Short-term PPI usage may increase the risk of community-acquired pneumonia. The risk does not appear elevated in long-term users. (Conditional recommendation, moderate level of evidence)
- 5. PPI therapy does not need to be altered in concomitant clopidogrel users as there does not appear to be an increased risk for adverse cardiovascular events. (Strong recommendation, high level of evidence)

Extraesophageal Presentations of GERD: Asthma, Chronic Cough, and Laryngitis

- 1. GERD can be considered as a potential co-factor in patients with asthma, chronic cough, or laryngitis. Careful evaluation for non-GERD causes should be undertaken in all of these patients. (Strong recommendation, moderate level of evidence)
- 2. A diagnosis of reflux laryngitis should not be made based solely upon laryngoscopy findings. (Strong recommendation, moderate level of evidence)
- 3. A PPI trial is recommended to treat extraesophageal symptoms in patients who also have typical symptoms of GERD. (Strong recommendation, low level of evidence)
- 4. Upper endoscopy is not recommended as a means to establish a diagnosis of GERD-related asthma, chronic cough, or laryngitis. (Strong recommendation, low level of evidence)
- 5. Reflux monitoring should be considered before a PPI trial in patients with extraesophageal symptoms who do not have typical symptoms of GERD. (Conditional recommendation, low level of evidence)
- 6. Non-responders to a PPI trial should be considered for further diagnostic testing and are addressed in the refractory GERD section below. (Conditional recommendation, low level of evidence)
- 7. Surgery should generally not be performed to treat extraesophageal symptoms of GERD in patients who do not respond to acid suppression with a PPI. (Strong recommendation, moderate level of evidence)

GERD Refractory to Treatment with PPIs

- 1. The first step in management of refractory GERD is optimization of PPI therapy. (Strong recommendation, low level of evidence)
- 2. Upper endoscopy should be performed in refractory patients with typical or dyspeptic symptoms principally to exclude non-GERD etiologies. (Conditional recommendation, low level of evidence)
- 3. In patients in whom extraesophageal symptoms of GERD persist despite PPI optimization, assessment for other etiologies should be pursued through concomitant evaluation by ear, nose, and throat (ENT), pulmonary, and allergy specialists. (Strong recommendation, low level of evidence)
- 4. Patients with refractory GERD and negative evaluation by endoscopy (typical symptoms) or evaluation by ENT, pulmonary, and allergy specialists (extraesophageal symptoms), should undergo ambulatory reflux monitoring. (Strong recommendation, low level of evidence)
- 5. Reflux monitoring *off* medication can be performed by any available modality (pH or impedance-pH). (Conditional recommendation, moderate level evidence) Testing *on* medication should be performed with impedance-pH monitoring in order to enable measurement of nonacid reflux. (Strong recommendation, moderate level of evidence)
- 6. Refractory patients with objective evidence of ongoing reflux as the cause of symptoms should be considered for additional anti-reflux therapies, which may include surgery or Transient Lower Esophageal Sphincter Relaxation (TLESR) inhibitors. (Conditional recommendation, low level of evidence) Patients with negative testing are unlikely to have GERD and PPI therapy should be discontinued. (Strong recommendation, low level of evidence)

Complications Associated with GERD

- 1. The Los Angeles (LA) classification system should be used when describing the endoscopic appearance of erosive esophagitis. (Strong recommendations, moderate level of evidence) Patients with LA Grade A esophagitis should undergo further testing to confirm the presence of GERD. (Conditional recommendation, low level of evidence)
- 2. Repeat endoscopy should be performed in patients with severe erosive reflux disease (ERD) after a course of antisecretory therapy to exclude underlying Barrett's esophagus. (Conditional recommendation, low level of evidence)
- 3. Continuous PPI therapy is recommended following peptic stricture dilation to improve dysphagia and reduce the need for repeated dilations. (Strong recommendation, moderate level of evidence)
- 4. Injection of intralesional corticosteroids can be used in refractory, complex strictures due to GERD. (Conditional recommendation, low level of evidence)

- 5. Treatment with a PPI is suggested following dilation in patients with lower esophageal (Schatzki) rings. (Conditional recommendation, low level of evidence)
- 6. Screening for Barrett's esophagus should be considered in patients with GERD who are at high risk based on epidemiologic profile. (Conditional recommendation, moderate level of evidence)
- 7. Symptoms in patients with Barrett's esophagus can be treated in a similar fashion to patients with GERD who do not have Barrett's esophagus. (Strong recommendation, moderate level of evidence)
- 8. Patients with Barrett's esophagus found at endoscopy should undergo periodic surveillance according to guidelines. (Strong recommendation, moderate level of evidence)

Definitions:

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system was used to evaluate the strength of the recommendations and the overall level of evidence.

The level of evidence could range from "high" (implying that further research was unlikely to change the authors' confidence in the estimate of the effect) to "moderate" (further research would be likely to have an impact on the confidence in the estimate of effect) or "low" (further research would be expected to have an important impact on the confidence in the estimate of the effect and would be likely to change the estimate).

The strength of a recommendation was graded as "strong" when the desirable effects of an intervention clearly outweigh the undesirable effects and as "conditional" when there is uncertainty about the trade-offs.

Clinical Algorithm(s)

The original guideline document contains a clinical algorithm for refractory gastroesophageal reflux disease (GERD).

Scope

Disease/Condition(s)

- Gastroesophageal reflux disease (GERD)
- "Refractory" GERD

Note: GERD should be defined as symptoms or complications resulting from the reflux of gastric contents into the esophagus or beyond, into the oral cavity (including larynx) or lung.

Guideline Category

| Assessment of | f Therapeutic | Effectiveness |
|---------------|---------------|---------------|
|---------------|---------------|---------------|

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Family Practice

Gastroenterology

| Internal Medicii |
|------------------|
| Pharmacology |

Surgery

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To review the presentations of any risk factors for gastroesophageal reflux disease (GERD), the diagnostic modalities and their recommendation for use and recommendations for medical, surgical and endoscopic management including comparative effectiveness of different treatment.
- To address extraesophageal symptoms and complications, as well as the evaluation and management of "refractory" GERD
- To address potential risks and side effects of the main treatments for GERD and their implications for patient management

Target Population

Patients with gastroesophageal reflux disease (GERD) or "refractory" GERD

Interventions and Practices Considered

Diagnosis

- 1. Diagnostic evaluation of non-cardiac chest pain
- 2. Endoscopy as indicated
- 3. Esophageal manometry (preoperative evaluation only)
- 4. Ambulatory esophageal reflux monitoring

Management

- 1. Weight loss if needed
- 2. Head of bed elevation and avoidance of meals 2-3 hours before bedtime
- 3. Routine global elimination of food that can trigger reflux is not routinely recommended in the treatment of gastroesophageal reflux disease (GERD)
- 4. Proton pump inhibitors (PPIs)
 - Eight-week course
 - Administered 30-60 minutes before meal
 - Once a day dosing before first meal of day
 - Non-responders should be referred for evaluation
 - For partial response, increase dose to twice daily therapy
 - Maintenance therapy
- 5. H₂-receptor antagonist therapy (as a maintenance option) in patients without erosive disease
- 6. Surgical options
 - Preoperative ambulatory pH monitoring and esophageal manometry
 - Gastric bypass surgery for obese patients

• Current endoscopic therapy or transoral incisionless fundoplication

Major Outcomes Considered

- Complications of gastroesophageal reflux disease (GERD), including erosive esophagitis (ERD), esophageal strictures and Barrett's
 esophagus
- · Association between GERD and obesity
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A search of OVID Medline, PubMed and ISI Web of Science was conducted for the years from 1960 – 2011 using the following major search terms and subheadings including "heartburn," "acid regurgitation," "GERD," "lifestyle interventions," "proton pump inhibitor (PPI)," "endoscopic surgery," "extraesophageal symptoms," "Nissen fundoplication," and "GERD complications." We used systematic reviews and meta-analyses for each topic when available followed by a review of clinical trials.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was used to evaluate the strength of the recommendations and the overall level of evidence.

The level of evidence could range from "high" (implying that further research was unlikely to change the authors' confidence in the estimate of the effect) to "moderate" (further research would be likely to have an impact on the confidence in the estimate of effect) or "low" (further research would be expected to have an important impact on the confidence in the estimate of the effect and would be likely to change the estimate).

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

See the "Rating Scheme for the Strength of the Evidence" field.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

See the "Rating Scheme for the Strength of the Recommendations" field.

Rating Scheme for the Strength of the Recommendations

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was used to evaluate the strength of the recommendations.

The strength of a recommendation was graded as "strong" when the desirable effects of an intervention clearly outweigh the undesirable effects and as "conditional" when there is uncertainty about the trade-offs.

Cost Analysis

- A meta-analysis found a high probability that non-cardiac chest pain responds to aggressive acid suppression. This study supported earlier
 work suggesting the efficacy and cost effectiveness of a proton pump inhibitors (PPI) trial (PPI twice daily in variable doses) in patients with
 chest pain in whom a cardiac cause had been excluded.
- Although the prevalence of eosinophilic esophagitis (EoE) in patients with refractory gastroesophageal reflux disease (GERD) in the US has
 not been studied, a recent Markov model found that obtaining esophageal biopsies to diagnose EoE in refractory GERD patients is costeffective only when the prevalence of EoE is 8% or greater.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

In an effort to make our new guidelines as "fresh" as possible when published, we have created a special guideline review process, involving members of the Board of Trustees, Practice Parameters Committee and the American Journal of Gastroenterology. It is our goal to review the guideline, allow you to revise the guideline, and re-review the guideline within 6 months of first submission. Therefore the entire process should take 1 year from commission to finished, accepted guideline.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Proper diagnosis and management of gastroesophageal reflux disease (GERD)
- Reduction of GERD related complications (including erosive esophagitis, stricture, and Barrett's esophagus)

Potential Harms

- Proton pump inhibitor (PPI) therapy can be a risk factor for Clostridium difficile infection, and should be used with care in patients at risk.
- Patients choosing to undergo surgical therapy for gastroesophageal reflux disease (GERD) may face some additional risks including increased short-term risk of mortality.

Contraindications

Contraindications

Achalasia or severe hypomotility (scleroderma-like esophagus) are conditions that would be contraindications to Nissen fundoplication.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Patient Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

| Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013 Mar;108(3):308-28. [184 references] PubMed |
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| Guideline Status |
| This is the current release of the guideline. |
| Guideline Availability |
| Electronic copies: Available from the American College of Gastroenterology Web site |
| Availability of Companion Documents |
| The following is available: |

• American College of Gastroenterology Practice Parameters Committee. Guideline development polices. 2010 Jan. Available from the

American College of Gastroenterology (ACG) Web site

Patient Resources

The following is available:

• Information on acid reflux is available on the American College of Gastroenterology's Patient Education & Resource Center Web site

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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